REMARKS

Rejection of claims under 35 U.S.C. 102:

Claims 1-6 and 12-17 are rejected under §102(a) as being anticipated by Hajjar *et al.* Applicants have submitted a §131 Declaration with this Amendment and Response which contains the signatures of all of the inventors to remove this prior art document.

Claims 1-6 and 12-20 are rejected under §102(e) as being anticipated by Isner *et al.* and Mann *et al.*

Regarding the Isner *et al.* reference: Applicants have amended the claim to substitute the term "injecting" in place of "introducing." The term "injecting" is first referenced in Applicants' specification on page 16, line 4. The Isner *et al.* reference coats the balloons on the catheter with nucleic acid, blows up the balloons and transfects endothelial cells by direct contact of the nucleic acid with the vessel wall. In contrast, Applicants inject their nucleic acid into the vascular fluid, which allows the nucleic acid to pass through the vessel walls into the heart muscle.

On page 6, the Action indicates that the delivery of a polynucleotide by means of single balloon catheter is not taught. Applicants point out that Example 3 teaches the use of a 7 Fr balloon-tipped triple lumen catheter (a single balloon catheter) as a preferred embodiment.

The Mann *et al.* reference describes processes to deliver nucleic acid to endothelial cells. It is important to note that the Mann *et al.* invasive processes use pressure applied to the targeted cell. In Column 10 beginning on line 33, the authors describe cell membrane permeability to nucleic acids is increased by applying pressure to the cell. The last paragraph of column 10 states "it is in general preferred that the walls of the pressurized enclosure do not include living tissue, since tissue forming parts of the enclosure wall is subject to mechanical stress. In such a case, it is important that a protective sheath means be used to prevent distension of the tissue."

In contrast, Applicants use the living tissue wall of the blood vessel as the pressurized enclosure. Applicants' process uses the blood vessel walls to provide the pressurized enclosure, subjecting them to mechanical stress, which pushes the nucleic acid out of the blood vessel into the surrounding muscle tissue. The process does not utilize the external pressure described in the Mann *et al.* reference nor the sheath mechanism. The claims have been amended to further clarify Applicants' process.

On page 7, the Action rejects claims 1-6 and 12-22 as being anticipated by the Wolff *et al.* US Patent 5,693,622.

Applicants have amended claims 1 and 18 to clarify that their process is directed to injecting the nucleic acid into a blood vessel. Conversely, the Wolff *et al.* patent discloses injecting nucleic acid directly into muscle using a vascular catheter.

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendments and discussion, it is submitted that claims 1-6 and 12-22 should be allowable and Applicants respectfully request an early notice to such effect.

Respectfully submitted,

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